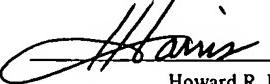


1638  
~~8-14-00~~  
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PATENT  
Docket No. 261922003302  
Client Ref. 46040 US C2 99

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, D.C. on August 1, 2000.

  
Howard R. Harris

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Albert J. J. VAN OOVEN *et al.*

Serial No.: 09/003,047

Filing Date: January 5, 1998

For: TRANSGENIC PLANTS HAVING A  
MODIFIED CARBOHYDRATE  
CONTENT



Examiner: Ousama M-Faiz Zaghmout, Ph.D.

Group Art Unit: 1638

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Applicant's call to the Examiner's attention that previously only a copy of the Declaration of Jan Pen, Ph.D. was available on June 12, 2000, at the time of the filing of the Amendment under 37 C.F.R. § 1.111. Enclosed please now find the original executed Declaration of Jan Pen, Ph.D.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this

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document to **Deposit Account No. 03-1952**, referencing **261922003302**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 1, 2000

Respectfully submitted,

By: \_\_\_\_\_

  
Thomas G. Wiseman  
Registration No. 35,046

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Declaration

in the United States Patent and Trademark Office

In re application of Albert J. J. Van Ooyen *et al.*

Serial No. 09/003,047

Filing date 01/05/98

Art unit 1649

For: Transgenic plants having a modified carbohydrate content

I, Jan Pen, have obtained a PhD in Biochemistry at the University of Groningen (The Netherlands) in 1986. I have been working in plant genetics in various functions at MOGEN International nv. since 1989.

1. The examiner has rejected claims 1, 27 to 28, 42, 48, 51 and 54 to 58 on grounds that these claims allegedly contain "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". I will address this issue in my capacity as a person skilled in the art to which this invention pertains.
2. The examiner states that "Applicants claim a method for modifying carbohydrate composition in any transgenic plant or plant organ by stably expressing any expression construct containing any microbial endo-glucanase under a 35S CaMV promoter. However, the specification does not teach those skilled in the art how to identify, characterize and test the nucleotide sequences encompassed by these claims". I submit that identification, characterisation and testing of nucleotide sequences (i.e., microbial endo-glucanases) encompassed by these claims could readily be carried out by a person skilled in the art using known techniques. For example, identification and characterisation of microbial endo-glucanases is not limited to new microbial endo-glucanases, but also covers incorporation of known microbial endo-glucanases in an expression construct. Nevertheless, new microbial endo-glucanases could readily be identified by, for example, sequence homology. Similarly, a person skilled in the art would merely use known techniques in the testing of the relevant nucleotide sequences.
3. The examiner proceeds to state "The specification does not teach if the nucleotide sequence from every microbe is identical, or if all nucleotide sequences of all microbial origin have a common property or physical characteristics". It would be apparent to a skilled person that the nucleotide sequence from every microbe is unlikely to be identical, but would comprise a degree of homology. It would also be apparent that the common property or physical characteristic sought would be the ability to express glucanase under the correct conditions.
4. Then the examiner states that "The specification does not teach those skilled in the art any step on how mutagenesis, modification, the alteration of the coding sequence around the translation initiation site to accommodate Kozak consensus sequence will be performed". The examiner further states that "The instant disclosure fails to teach the factors which are essential for successfully expressing a glucanase gene of microbial origin". All these techniques mentioned by the examiner are merely routine and well known to persons skilled in the art and therefore, it would not have been necessary to have included all these details in the specification. More importantly, the expression of many microbial endo-glucanase would not require modification of the coding sequence and in such situations the above techniques listed by the examiner would be irrelevant. Genes of microbial origin that can profit from modification of the coding sequence

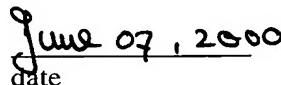
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exist, but mostly the genes of microbial origin do not require such modification for basic plant expression and modification of the coding sequence only will further improve expression. Thus, such genes would be readily apparent to persons skilled in the art.

5. The examiner elaborates on the objection concerning modification of the coding sequence, stating that "modification of the coding sequence to enhance the expression of non-plant gene in plants requires many steps which have not been addressed in the instant disclosure which include: changes in localisation of the regions of A+T richness to resemble the plant introns, and the optimisation of the potential plant polyadenylation signal sequences, ATTTA sequences to avoid any destabilisation of the mRNA in the plant". Again, my above comments apply that these modifications will normally improve expression levels obtained through expression of the non-modified genes. In situations where modification of the coding sequence is required, the above mentioned techniques are known to a person skilled in the art and the skilled person would also be able to use them to obtain the desired effect.
6. The examiner then objects that "the process of transforming plants with individual genes to obtain desired phenotypes is unpredictable". I submit that the examiner's opinion is misconceived. The technique of transformation is routine and, at the time of filing the present invention, there were numerous published examples demonstrating the successful transformation of both monocots and dicots. The technique of transformation may be unpredictable to the extent that some plants will not contain the desired gene of interest, however, these plants can readily be identified with the aid of a suitable selection marker. Further, although there are examples where it is shown that it may be possible to obtain a transgenic plant with a transgene which does not express the desired trait, it is submitted that in the case of expression of microbial genes in eukaryotic organisms normally phenotypes are obtained. Use of microbial genes normally will not give rise to product inhibition in biosynthetic pathways which is the most common reason for the absence of phenotypes in transgenics. Further, in case that nevertheless such a phenomenon may occur, I submit that such transgenic plants will be selectively discarded in preference to plants containing the gene of interest which express the desired trait.
7. In conclusion, I do not believe that the present invention would cause undue burden upon a person skilled in the art. The "trial-and-error" which the examiner refers to is not specific to the present invention, but more accurately relates to the nature of the experimental techniques employed to work the invention and would be accepted by a person skilled in the art as being within the realms of routine experimentation.

The undersigned declares further that all statements of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant document and of application Serial No. 09/003,047 or any patents issuing thereon to which the instant document refers.

  
Dr. Jan Pen

  
date